

REPLACEMENT SHEET

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CLAIMS

- Sil B1*
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1. A stable, liquid pharmaceutical formulation comprising interferon-beta, a stabilising amount of a polyol, and a buffer capable of maintaining the pH of the formulation at a value between 3.0 and 4.0.
- a lab 72/10*
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2. A liquid pharmaceutical formulation according to claim 1, wherein the polyol is mannitol.
- a*
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3. A liquid pharmaceutical formulation according to *any of the claims 1 or 2*, in which interferon-beta is recombinant.
- a*
4. A liquid pharmaceutical formulation according to *any of the preceding claims*, in which interferon-beta is in a quantity between 0.6 and 1 MIU/ml.
- a*
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5. A liquid pharmaceutical formulation according to *any of the preceding claims*, in which the buffer solution is acetate buffer.
- a*
- 25
6. A liquid pharmaceutical formulation according to claim 4, in which the buffer solution has a concentration of 0.01 M.
- a*
7. A liquid pharmaceutical formulation according to *any of the claims from 1 to 6*, which also comprises human albumin.
- a*
- 30
8. A liquid pharmaceutical formulation according to *any of the claims from 1 to 7*, comprising 1 MIU/ml of interferon-beta, 54.6 mg/ml of mannitol, 0.5 mg/ml of albumin in a solution of 0.01 M acetate buffer at pH 3.5.
- a*
9. Process for the preparation of a liquid pharmaceutical formulation according to *any of the claims from 1 to 8*, comprising the dilution of interferon-beta with a solution of excipients.

REPLACEMENT SHEET

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10.A container hermetically sealed in sterile conditions comprising the
~~claim~~,
liquid pharmaceutical formulation according to any of the claims from 1
to 8 and appropriate for storage prior to use.

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